# A CLINICAL STUDY OF JANUDHARA KARMA WITH TIL TAIL (SESAME OIL) IN THE MANAGEMENT OF JANU-SANDHIVATA (KNEE OSTEOARTHRITIS)

# SYNOPSIS

**FOR**

**DEGREE OF *AYURVEDA VARIDI***

**Ph.D.(Ayu)**


**SUPERVISOR**

**Dr. Brahmanand Sharma**
M.D., PhD(Ayu)
Associate Professor
P.G. Department of Kayachikitsa

**SCHOLAR**

**Dr. Gyan Prakash Sharma**
M.D.(Panchakarma)
Associate Professor
P.G. Department of Panchakarma



**P.G. DEPARTMENT OF KAYA CHIKITSA**

**UNIVERSITY COLLEGE OF AYURVEDA, JODHPUR.**

**DR. SARVEPALLI RADHAKRISHNAN RAJASTHAN AYURVED UNIVERSITY,**

**JODHPUR**

**Application for Dissertation**

To

The Registrar,

Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University,

Jodhpur, Rajasthan.

**THROUGH** – HOD , P.G. Department of KayaChikitsa

**SUBJECT**- Registration of the dissertation for the award of Ayurveda Varidi [PhD.(Panchakarma)] in the

P.G. Department of Panchakarma in the faculty of Ayurveda, during the session 2019

Respected Sir,

With due regards I am Gyan Prakash Sharma Ph.D scholar in Panchakarma Department of University college of Ayurveda is submitting my synopsis with suggest recommendation with necessary Particulars for your kind perusal & permission please.

| | |
|---|---|
| Name of Scholar | : Gyan Prakash Sharma |
| Father's Name | : Shiv Kumar Sharma |
| Date of Birth | : 01/04/1980 |
| Permanent address | : B 108,Ganga Sagar Vaishali Nagar, Jaipur |
| Last examination passed | : M.D. 2009 |
| Enrollment No. | : RAU/06/1390 |
| Name of Department | : P.G. Department of Panchakarma |

Topic of Dissertation:

**A CLINICAL STUDY OF JANUDHARA KARMA WITH TIL TAIL(SESAME OIL) IN THE MANAGEMENT OF JANU-SANDHIVATA (KNEE OSTEOARTHRITIS)**

**SUPERVISOR**

DR. BRAHMANAND SHARMA
M.D.,PhD (Ayu.)
Associate Professor
P.G. Department. of Kayachikitsa

**SCHOLAR**

DR. GYAN PRAKASH SHARMA
M.D. (Panchakrma)
Associate Professor
P.G. Department of Panchakarma

# A CLINICAL STUDY OF JANUDHARA KARMA WITH TIL TAIL(SESAME OIL) IN THE MANAGEMENT OF JANU-SANDHIVATA (KNEE OSTEOARTHRITIS)

## INTRODUCTION:

Osteoarthritis (OA) is a long-term chronic disease characterized by the deterioration of cartilage in joints which results in bones rubbing together and creating stiffness, pain, and impaired movement. Osteoarthritis (OA) is a chronic degenerative disorder of multifactorial etiology characterized by the loss of articular cartilage, hypertrophy of bone at the margins, subchondral sclerosis, and range of biochemical and morphological alterations of the synovial membrane and joint capsule

Pathological changes in the late stage of OA include softening, ulceration, and focal disintegration of the articular cartilage. Synovial inflammation also may occur. Osteoarthritis is the single most common cause of disability in older adults (40 to 65). Osteoarthritis is the second most common rheumatologic problem and it is the most frequent joint disease with a prevalence of 22% to 39% in India. OA is more common in women than men, but the prevalence increases dramatically with age. Nearly, 45% of women over the age of 65 years have symptoms while radiological evidence is found in 70% of those over 65 years. OA of the knee is a major cause of mobility impairment, particularly among females. OA was estimated to be the 10$^{th}$ leading cause of nonfatal burden. According to the United Nations, by 2050 people aged over 60 will account for more than 20% of the world's population of that 20%, a conservative estimate of 15% will have symptomatic OA, and one-third of these people will be severely disabled. This means that by 2050, 130 million people will suffer from OA worldwide, of whom 40 million will be severely disabled by the disease.

Costs associated with OA include costs for adaptive aids and devices, medicines, surgery, and time off at work. Osteoarthritis is currently diagnosed by physical examination and, where necessary, with x-ray, MRI scan and arthroscopy. However, these diagnostic tools have low sensitivity and specificity. There are no biomarkers for OA that can be used in clinical practice at this time. The treatment of OA involves: treating associated pain; viscos supplementation with intra-articular hyaluronate injections; intra-articular corticosteroid injections; joint replacement surgery; and, in rare circumstances, autologous chondrocyte implantation into the damaged areas..

In Ayurveda, the disease Sandhivata resembles with osteoarthritis. It commonly presents unilaterally in the knee joint, which is the most important weight bearing joint in the body. Osteoarthritis of the knee joint is the most common joint disorder seen in elderly people and obese person.Various Ayurvedic literatures have mentioned the features of Sandhigata vata as

वातपूर्णदृतिस्प ार्शः भोथः संधिगतेऽनिले ।

प्रसारणाकुञ्चनयोः प्रवृति च सवेदना ।। (च.चि 28/37)

हन्ति संधिगतः संधीन् भूल गोफौ करोति ।। (सु.नि. 1/28)

सर्पिस्तैलवसामज्जासेकाभ्यञ्जनबस्तय:

स्निग्धा: स्वेदा निवातं च स्थानं प्रावाराणानि च (च चि 28/105)

## AIMS & OBJECTIVE OF THE STUDY

- To study the conceptual and clinical aspect of the disease of janu-sandhivata (knee osteoarthritis) as per Ayurved and modern medical science. •
- To analyze the efficac **of janudhara karma with til tail(sesame oil) in management of janu-sandhivata (knee osteoarthritis)**
- The result will be evaluated in the clinical parameter obtained before & after the completion of treatment.
- Observed data will be tabulated & analyzed statistically with parametric and non parametric data relevant t test & Wilcoxon test & level of significance, p value will be reported.

## NEED OF STUDY-

OA is the most prevalent type of cartilage degenerative disease, the other being rheumatoid arthritis. OA results in progressive cartilage degradation characterized by the softening, fibrillation and erosions of the articular surface According to modern point of view it is mentioned that Osteoarthritis (OA) shows a strong association of ageing, produces pain and disability in the elderly. In OA, besides cartilage erosion in subchondral bone, synovial fluid, and the synovial membrane also play a role in the progression of OA. Osteophyte formations, subchondral bone remodeling, and synovial membrane inflammation may further aid in cartilage tissue degradation.

## RISKS OF KNEE REPLACEMENT SURGERY

Knee replacement surgery carries many different risks. Some result directly from the surgery, while others stem from the body's reaction to the operation.

- ✓ Anesthesia ,Infection,Bleeding,Bloodclots
- ✓ Pain and swelling,Breathing problems,Nerve and artery damage
- ✓ Allergic reaction,Implant failure,Venous thromboembolism

In the present era, modern medicines have gained wide acceptance and the knowledge regarding the disease and treatment has ascended to its peak. A lack a satisfactory regimen is not yet available in the field of health which can roll back the wear and tear of joints. So in order to obtain a permanent and safest remedy this problem will selected in the present study. This will help improve disease monitoring and help facilitate the development of medicines that can reverse the progression of this high-burden condition. There is currently a need for research in the following areas:

The cost-effectiveness, safety, and efficacy of the long-term management of OA with the currently available pharmaceutical therapies

There are still many questions to be answered. There are no drugs today that can stop or reverse the process. Therefore, a great deal of work is still needed to understand this degenerative disease, and for the development of therapeutics to stop the progression of OA.

Snehan and swedan including Janudhara both are local therapeutic procedures. According to retention of time and temperature with specific oil increase blood circulation of particular area then time of position also help to reform cartilage and relax supporting ligament and muscles.

स्नेहोपनाहाग्निकर्मबन्धनोन्मर्दनानि च। स्नायुसन्ध्यस्थिसंप्राप्ते कुर्याद्वायावतन्द्रित : ।। (सु.चि. 4/8)

Sandhivata is vata disorder .According to Ayurveda, Snehana, Svedana , Dahana and Upanaha are the prime modalities of treatment in the management of Sandhigata vata. These are mostly aimed at Bramhana. Sushruta has mentioned the treatment for Sandhigatavata as Snehana. Snehan can be done by various methods,in this study a clinical study of janudhara karma with TilTail in management of Janu-sandhivata (knee osteoarthritis)

## MATERIALS AND METHODS

### Study Design

| | TYPE OF STUDY | INTERVENTIONAL TRIAL |
|---|---|---|
| | Level of study | OPD/IPD |
| | Masking | Open label |
| | Timing | Prospective |
| | End Point | Efficacy and Safety |
| | Number of Group | One |
| | Sample Size | 100 |
| | Treatment Period | 63 DAYS<br>(14 Days Process then 7 Days Rest conti. to 63 days) |
| | Follow up Period | 63rd Day , 90th Day |

**Sample Source**:

In this study total sample of 100 patients will be registered for the research work and the patients will be collected from both O.P.D and I.P.D of Panchakarma dept. DSSRAU,Jodhpur for Janudhara by Til Tail

**Sample Size** = 100

**Type of study** -It is a Single Arm , Prospective, Open Study

**Group-** Single Group 100 well diagnosed patients as per CRF of Janu-Sandhigatavata will be done Janudhara with Til tail for 63 days.

### METHOD:

**POORV KARMA:**

Patient is advised to lie down in supine position and to sit comfortably with affected knee joint exposed. Mridu Abhyang(Massage) will be done for 5 minute over affected area with 40 degree Celsius.

### PRADHANA KARMA

**JANUDHARA :**

In this process Patient is asked to lie down in supine position and to sit comfortably with affected knee joint exposed. Like shirodhara method, tail dhara from is continuously dropped over with 4 angul ( 8cm) height on the affected joint with & 40 degree Celsius . Dhara is dropped over both anterior and posterior part of Knee joint.. Tail is kept at constant temperature. The process will be carried out for 30 minutes with recycling.

### PASHCHAT KARMA:

**P**atient will be sit in rest room for 15 minute with avoiding Cold Air & Atmosphere.

### DURATION & DOSE:

**Janudhara P**rocess will be carried out for 63 days **( 14 Days Process then 7 Days Rest till 63 days)** with using 1 liter oil per sitting.

**Follow up :** $63^{rd}$ day, $90^{th}$ day

**DRUG REVIEW:**

**Til Tail (SESAME OIL)**

Latin Name: *Sesamum Indicum* Family: Pedaliaceae

Parts Used: Seed oil (as per API)

रस पञ्चक

रस: मधुर कटु तिक्त कषाय ,गुण: गुरु, स्निग्ध,वीर्य: उष्ण,विपाक: मधुर ,दोषघ्नत: वातशामक, कफपित्तशामक

Chemical Constituents: arginine, cystine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, tyrosine, valine, & globulins, p-aminobenzoic acid, ascorbic acid, biotin, choline, folic acid, inositol, niacin, nicot Sesamol and sesaminol, neutral lipids, glycolipids,phospholipids.Sesamol, two phenolic antioxidants and sesaminol sesame oil is mostly composed of tryglycerides of the singly unsaturated oleic acids(40%) and the doubly unsaturated linolic acid (45%), saturated fat (10%).Seed: protein content of the seed is 21.5 %, the fat content is 60.8 %, the carbohydrate content is 8.9 %, and the ash content is 3.4 %. Unsaturated fatty acids, calcium, and vitamins A, B, and E are abundant.

" Bahyabhyantaratah snehe aathimajjahatam jayet|| C .C. 28/93

"Vatasyopakramah snehah swedah sanshodhanam mrudu ||" A.H S.

**1. INCLUSION CRITERIA:**

1. Patients fulfilling the Diagnostic criteria of Sandhigatavata (OA of knee)

2. Patients age group between 40 to 70 years both male and female.

3. OA Grade 0 to 3 KL system ( kellgren & Lawrence System) Grading:-

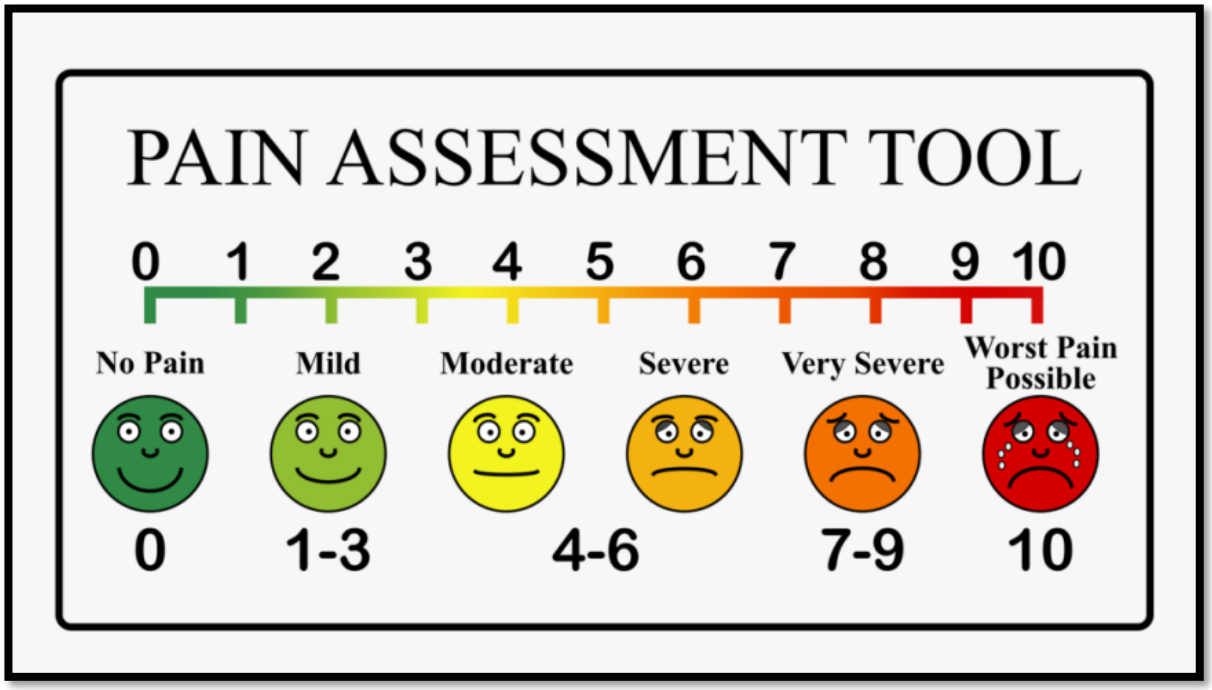
(Grade 0 – (None) absence of x Ray change in OA, Grade 1 ( Doubltful) Joint Narrowing & Possible Osteophyte lipping,Grade 2 ( Minimum) Joint Narrowing & Osteophyte ,Grade 3( Moderate) Joint Narrowing & multiple Osteophyte

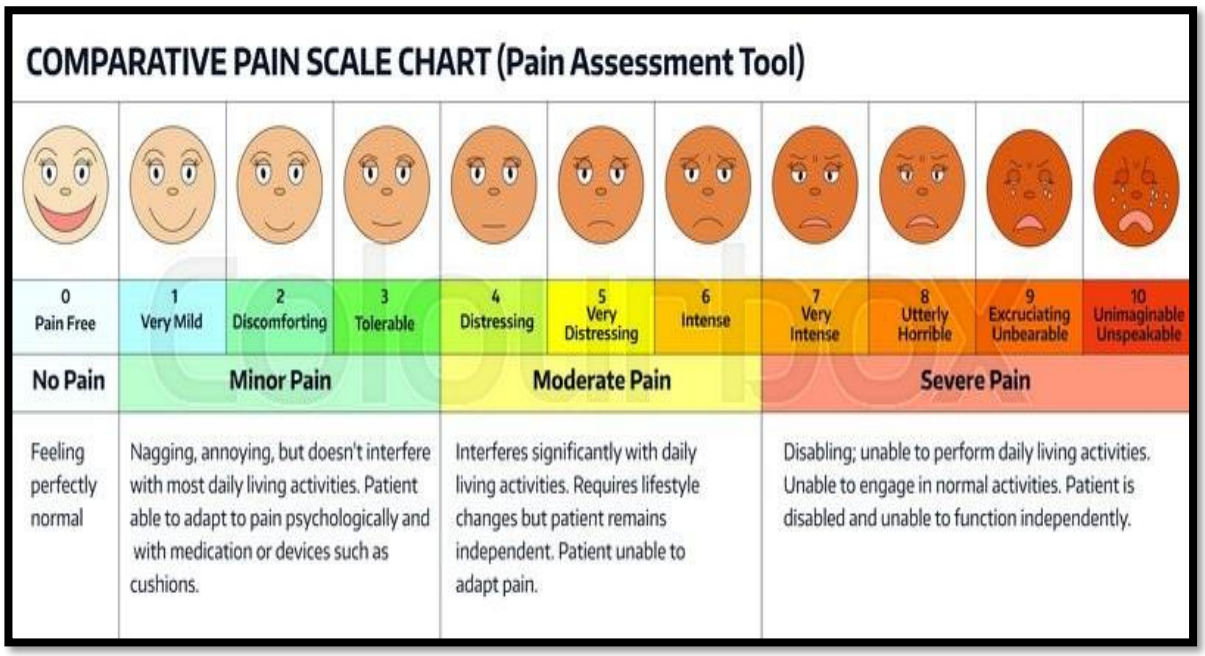
4.Patients willing to give written consent.

**DIAGNOSTIC ASSESSMENT CRITERIA**

- Sandhishoola (Pain in knee joints)
- Sandhishotha ( Knee joint swelling)
- Sandhiatopa (Crepitation)
- Prasaranaaakunchanayo pravruttischavedana (Painful joint movement)

- **Knee joint X-ray** will be taken before the start of process and after the completion of process.
- **Knee Injury and Osteoarthritis Outcome Score(KOOS)**
- **VAS - Visual Analogue Score for Pain Assessment**





COMPARATIVE PAIN SCALE CHART (Pain Assessment Tool)
0 Pain Free
1 Very Mild
2 Discomforting
3 Tolerable
4 Distressing
5 Very Distressing
6 Intense
7 Very Intense
8 Utterly Horrible
9 Excruciating Unbearable
10 Unimaginable Unspeakable
No Pain
Minor Pain
Moderate Pain
Severe Pain
Feeling perfectly normal
Nagging, annoying, but doesn't interfere with most daily living activities. Patient able to adapt to pain psychologically and with medication or devices such as cushions.
Interferes significantly with daily living activities. Requires lifestyle changes but patient remains independent. Patient unable to adapt pain.
Disabling; unable to perform daily living activities. Unable to engage in normal activities. Patient is disabled and unable to function independently.

## Knee Injury and Osteoarthritis Outcome Score(KOOS)

.Today's date: /_____/_____Date of birth:__/_____/_____

Name: _____

# INSTRUCTIONS:

This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and howwell you are able to perform your usual activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

### Symptoms

These questions should be answered thinking of your knee symptoms duringthe **last week**.

S1. Do you have swelling in your knee?

| Never | Rarely | Sometimes | Often | Always |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

S2. Do you feel grinding, hear clicking or any other type of noise when your kneemoves?

| Never | Rarely | Sometimes | Often | Always |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

S3. Does your knee catch or hang up when moving?

| Never | Rarely | Sometimes | Often | Always |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

S4. Can you straighten your knee fully?

| Always | Often | Sometimes | Rarely | Never |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

S5. Can you bend your knee fully?

| Always | Often | Sometimes | Rarely | Never |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

### Stiffness

The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

S6. How severe is your knee joint stiffness after first wakening in the morning?

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

S7. How severe is your knee stiffness after sitting, lying or resting **later in the day**?

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

## Pain

P1. How often do you experience knee pain?

| Never | Monthly | Weekly | Daily | Always |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

What amount of knee pain have you experienced the **last week** during the following activities?

P2. Twisting/pivoting on your knee

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

P3. Straightening knee fully

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

P4. Bending knee fully

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

P5. Walking on flat surface

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

P6. Going up or down stairs

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

P7. At night while in bed

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

P8. Sitting or lying

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

P9. Standing upright

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

## Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the**last week** due to your knee.

A1. Descending stairs

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A2. Ascending stairs

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A3. Rising from sitting

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A4. Standing

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A5. Bending to floor/pick up an object

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A6. Walking on flat surface

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A7. Getting in/out of car

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A8. Going shopping

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A9. Putting on socks/stockings

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A10. Rising from bed

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A11. Taking off socks/stockings

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A12. Lying in bed (turning over, maintaining knee position)

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A13. Getting in/out of bath

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A14. Sitting

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A15. Getting on/off toilet

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

A17. Light domestic duties (cooking, dusting, etc)

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

## Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.

SP1. Squatting

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

SP2. Running

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

SP3. Jumping

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

SP4. Twisting/pivoting on your injured knee

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

SP5. Kneeling

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

## Quality of Life

Q1. How often are you aware of your knee problem?

| Never | Monthly | Weekly | Daily | Constantly |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

Q2. Have you modified your life style to avoid potentially damaging activitiesto your knee?

| Not at all | Mildly | Moderately | Severely | Totally |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

Q3. How much are you troubled with lack of confidence in your knee?

| Not at all | Mildly | Moderately | Severely | Extremely |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

Q4. In general, how much difficulty do you have with your knee?

| None | Mild | Moderate | Severe | Extreme |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

## EXCLUSION CRITERIA:

- Patients with secondary arthritis , rheumatoid arthritis, gouty arthritis.
- Patients having history of joint trauma and other systemic illness.

## RESULTS

The grading of assessment criteria will be analyzed statistically in expressions of mean score (X) of B.T. (Before Treatment), A.T. (After Treatment), Standard deviation (S.D), Standard Error (S.E), P value. The signs and symptoms will be assessed before& after the treatment based on the assessment criteria. Parametric & Non parametric test, t test, Wilcoxon test .The observation of X-ray will be assessed .

**PROPOSED CONTENT OF DISSERTATION: -**

All the observations recorded and results obtained will be computed statistically to draw various conclusions. The project will be in the form of a thesis with following contents –

Benediction
Tribute
Acknowledgement

1. **Retrospection-**
Criteria of selection of topic
Aims & Objectives
**2. Research Methodology**
Method and Material of clinical study
**3. Literay & Clinical Review**
Ancient view – Ayurveda literature of the topic concerned , Pathogenesis, Clinical diagnostic measures, treatment & Analytical elaboration.
Modern view – Modern literature of the topic concerned, Pathogenesis, Clinical diagnostic measures, treatment & Analytical elaboration.
**4.Drug review –**
Pharmaceutical aspect- Prepration ,dose and descrition of drug
**5Applied experimental & clinical study**
Criteria of selection of patient
Clinical examination and Investigation
Differentional diagnosis
Diagnosis
**6.Result and analysis**
**7. Summary**
**8. Conclusion**
**9. Epilogue**
Referance/ Bibliography
**Informed consent Form, CRF, ADR Form**
Declaration